

Cipcin-DX

Ciprofloxacin 0.3% & Dexamethasone 0.1%

Sterile and Pyrogen free Eye/Ear Drops

Composition

Each ml contains Ciprofloxacin Hydrochloride BP equivalent to Ciprofloxacin 3 mg and Dexamethasone BP 1 mg. Preservative: Benzalkonium Chloride BP 0.1 mg.

Description

It is a sterile and pyrogen free ophthalmic solution containing Dexamethasone - a corticosteroid and Ciprofloxacin - a quinolone derivative for topical administration to the eyes.

Clinical Pharmacology

Dexamethasone reduces prostaglandin synthesis by inhibiting the enzyme phospholipase A₂. Also, Dexamethasone inhibits the chemotactic infiltration of neutrophils into the site of inflammation.

Ciprofloxacin has in vitro activity against a wide range of gram-negative and gram-positive organisms, possessing the greatest antibacterial activity of all quinolones. The bactericidal action of Ciprofloxacin results from interference with the enzyme DNA gyrase which is needed for the synthesis of bacterial DNA.

Indications and Uses

Acute and chronic keratitis and conjunctivitis of an infectious, allergic but non-viral nature.

It is also indicated in chronic anterior uveities, scleritis, episcleritis, myositis and corneal injury from chemical radiation or thermal burns, or penetration of foreign bodies.

Post-operative management of cataract, glaucoma, and strabismus.

The use of combination with an anti-infective component is indicated where the risk of superficial ocular infection is high.

Dosage and Administration

1 drop into conjunctival sac(s) every four to six hours. During the initial 24 to 48 hours, the dosage may be increased to 1 drop every two hours.

Contraindications

Known hypersensitivity to any ingredient of the product. Herpes simplex and other viral conditions, mycosis, glaucoma, newborn babies, fungal diseases of ocular or auricular structures

Precautions

Prolonged use may result in overgrowth of non-susceptible organisms including fungi; in ocular hypertension, damage to the optic nerve, defects in visual acuity and posterior sub capsular cataract formation may occur. Patients wearing contact lenses must not use the drops during the time the lenses are worn.

Side-Effects

Frequently reported adverse reactions are transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, photophobia, conjunctivitis/keratitis, Periocular/facial edema, foreign body sensation, blurred vision, tearing, dryness, and eye pain. Elevation of IOP with development of glaucoma, and delayed wound healing may rarely occur.

Pediatric

Safety & effectiveness for the use of this eye drops in children below the age of one year have not been established.

Use in Pregnancy & Lactation

Pregnancy:

It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mother:

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in human milk. So caution should be exercised when the combination is administered to a nursing woman.

Drug Interactions

Specific drug interaction studies have not been conducted with ophthalmic Ciprofloxacin and Dexamethasone. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, enhance the effects of the oral anticoagulant warfarin and its derivatives and have been associated with transient elevations in serum creatinine in patients receiving cyclosporin concomitantly.

Overdosage

Not known and not likely.

Pharmaceutical Precautions

Store at room temperature, protect from light. It is desirable that the contents should not be used more than one month after first opening of the bottle.

Commercial Pack

Plastic dropper bottle of 5 ml.

Manufactured by

Popular Pharmaceuticals Ltd. for



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.